

REMARKS

Claims 1-18 are pending. Claims 12-18 have been canceled without prejudice in response to a restriction requirement (see below). Claims 1 and 6 have been amended in order to clarify the scope of the invention. No new matter has been introduced as a result of the amendments.

1. Response to restriction requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:  
Group I. Claims 1-11, drawn to a method of regenerating a biosensor.  
Group II. Claims 12-18, drawn to a system for continuous monitoring of analytes.

Applicant respectfully responds as follows:

Applicant hereby elects Group I with traverse, i.e., claims 1-11, drawn to a method of regenerating a biosensor. The claims in Group I i.e., claims 1-11, are drawn to a method of regenerating a biosensor, while the claims in Group II are drawn to a system for continuous monitoring of analytes. Inasmuch as the system for continuous monitoring of analytes inherently comprises the use of biosensors and their regeneration, there is no additional burden on the part of the Patent Office to keep the claims of Group I together with the claims of Group II. Moreover, according to MPEP § 803, if the search and examination of patent claims can be made without serious burden, the examiner must examine it on the merits, even though the application includes claims to independent or distinct inventions.

Nevertheless in an effort to further prosecution, Applicant affirms the provisional election of claims 1-11 in Group I made by telephone August 27, 2003, and hereby cancels claims 12-18 without prejudice. Applicant further expressly reserves the right to

prosecute the subject matter of claims 12-18 in one or more divisional and/or continuing applications.

2. Response to rejection of claims under 35 U.S.C. § 103

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Luong et al as well as over Edelmann et al. in view of Wong.

Applicant respectfully responds as follows:

To establish a prima facie case of obviousness, **three basic criteria** must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference(s) when combined must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

**A Motivation to Combine Must Be Shown**

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). A mere conclusory statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings

of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). The Federal Circuit in *In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001), noted that “deficiencies of the cited references cannot be remedied by the Board’s general conclusions about what is ‘basic knowledge’ or ‘common sense’ to one of ordinary skill in the art. *Id.* at 1697. In other words, *In re Zurko* expressly proscribes any reliance by an examiner on what constitutes the knowledge of one skilled in the art, when the assessment of that knowledge is not based on any evidence in the record. More recently, the Federal Circuit reiterated this position in *In re Lee*, where it took issue with the fact that “neither the examiner nor the Board adequately supported the selection and combination of the … references to render obvious that which [patentee] described.” *In re Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002).

If a proposed modification would render the prior art teaching being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

#### **There Must Be a Reasonable Expectation of Success**

The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986). Evidence showing that there is no reasonable expectation of success supports a finding of nonobviousness. *In re Rinehart*, 531 F.2d 1048 (C.C.P.A. 1976).

#### **All Claim Limitations Must Be Taught or Suggested**

To establish prima facie obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). In other words, “[a]ll words in a claim must be considered in judging

the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382 (C.C.P.A. 1970).

Examiner has not established a *prima facie* case of obviousness. Examiner has failed to demonstrate any of the criteria required for a showing of *prima facie* obviousness, particularly, the requirements that there be a suggestion or motivation to modify the cited references or combine the reference teachings, and that all of the claim limitations be taught or suggested by the prior art. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

The claimed invention is drawn to a method of regenerating a biosensor wherein a biosensor that measures the levels of one or more components in a sample, is regenerated by washing. As set forth in claim 1, the regeneration (washing) of the biosensor occurs by varying the background flow of buffer fluid. In other words, as set forth in claim 1, the measurement of the sample is seamlessly integrated with the washing/regeneration process. None of the references cited by the Examiner teach the claimed invention.

Luong et al. discloses a biosensor and its use, but does not teach the regeneration of the biosensor by increasing the background flow of the buffer fluid. According to the Examiner, it would have been obvious to one of ordinary skill in the art to increase the washing buffer flow “because Luong emphasizes that slow dissociation of interfering glutamate leads to a non-zero baseline and that increased buffer flow increases dissociation of glutamate.” *See* Examiner’s Office Action at p.4. In support of this proposition, Examiner cites Luong et al. at col. 8, lines 56-64. *See* Examiner’s Office

Action at p.3. Applicant respectfully disagrees with Examiner's statements because although Luong teaches that varying the *sample stream flow rate* can have an effect on the glutamate binding capacity of the resin column, *see* Luong et al. at col. 8, lines 59-61, it does not teach that varying the *flow rate of the buffer fluid* can have an effect on the regeneration of a biosensor. Under the teachings of *In re Zurko* (see above), Examiner's reliance on the knowledge of one of ordinary skill in the art, is improper when the assessment of that knowledge is not based on any evidence in the record. Indeed, Examiner has repeatedly referred to various aspects of the claimed invention and stated that “[i]t would have been obvious to one of ordinary skill in the art to ...”, but has failed to point to any objective evidence in the record that would support these assertions.

Furthermore, the Examiner has combined the Edelmann and Wong references without making a showing of the requisite motivation to do. Under the teachings of *In re Fine*, *In re Zurko* and *In re Lee*, mere conclusory assertions stating that the references relied upon teach all aspects of the claimed invention is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. Notwithstanding the improper combination of the references, Applicant respectfully submits that the combination of Edelmann et al. and Wong does not result in the claimed invention. Examiner states that the turbulent flow of buffer disclosed by Wong is the same as increasing the flow rate of the buffer, and therefore results in the claimed invention when Wong is combined with Edelmann. The Examiner has liberally interpreted the disclosure of Wong to include elements not in evidence or otherwise disclosed. To state that the turbulent flow of buffer disclosed in Wong is the same as the

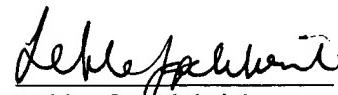
measured increased flow rate of buffer claimed in the present invention is neither correct nor grounded in objective evidence.

**CONCLUSION**

In conjunction with the claim amendments and arguments set forth above, Applicant believes that they have addressed all of the Examiner's concerns and rejections. Applicant believes that the claims are now in condition for allowance and respectfully requests that the Examiner grant such an action. If any questions or issues remain in the resolution of which the Examiner feels will be advanced by a conference with the Applicant's attorney, the Examiner is invited to contact the attorney at the number noted below.

A Petition for Extension of One-Month Extension of Time in which to file a response is being submitted concurrently with the response along with a check in the amount of \$55. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account 10-0447 (Reference No. 45687-00008).

Respectfully submitted,



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